U.S. Attorneys » District of Massachusetts » News

Department of Justice

U.S. Attorney's Office

District of Massachusetts

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Government Files Lawsuit against Hyannis Company Selling Unapproved "Medical Treatments"

Civil Action is Part of Nationwide Sweep in Dietary Supplement Market

BOSTON – The U.S. Attorney's Office announced today that it has sued to enjoin Hyannis-based Lehan Enterprises, Inc., doing business as Optimum Health Services, and its principal, Lesa Sverid, for violating the Food, Drug and Cosmetic Act in connection with their marketing and sale of purported medical treatments containing dimethyl sulfoxide (DMSO), a solvent derived from wood pulp.

The injunction is part of a coordinated nationwide sweep by the Department of Justice and federal partners pursuing civil and criminal cases against more than 100 makers and marketers of dietary supplements. The actions are the result of a year-long effort, begun in November 2014, to focus enforcement resources in the dietary supplement market which is causing increasing concern among health officials.

"Marketing products as treatments for disease when those products lack FDA approval presents potential health risks to consumers because the products may not be safe or effective," said United States Attorney Carmen M. Ortiz. "Consumers seeking relief from diseases and medical conditions should review FDA-approved products with a medical professional to avoid gambling with their health."

The complaint filed on behalf of the Food and Drug Administration (FDA) in the District of Massachusetts, alleges that Optimum and Sverid have been marketing their products—DMSO Cream, DMSO Cream with Aloe Vera, and DMSO Roll On—as topical treatments for diseases and medical conditions such as arthritis, cancer, herpes, and cataracts, even though the FDA has not approved the products. The government further alleges that the products do not bear adequate instructions for use by consumers.

The Food, Drug and Cosmetic Act authorizes the federal courts to enjoin permanently the introduction of unapproved new drugs or misbranded drugs into the market. The FDA drug approval process and labeling requirements are designed to ensure that drugs are safe and effective and that they bear adequate instructions for health care professionals and patients to use the products and understand the risks.

This case is among 25 civil actions pursued by the Justice Department's Consumer Protection Branch, U.S. Attorney's Offices and the Federal Trade Commission between November 2014 and November

2015. To date, courts have entered judicial orders in 11 cases, requiring dietary supplement makers to change their business practices to ensure that they are selling their products in compliance with the law.

For more information for athletes and general consumers to help realize, recognize and reduce the risks associated with using supplement products, visit the U.S. Anti-Doping Agency's website . To better understand the range of dietary supplement products and claims, the potential risks of taking supplements and questions to ask a health care professional before taking any supplements, visit the Federal Trade Commission's website.

U.S. Attorney Ortiz and Antoinette V. Henry, Special Agent in Charge of the U.S. Food and Drug Administration, Office of Criminal Investigations, Metro Washington Field Office, made the announcement today. This case is being handled by Assistant U.S. Attorney Deana El-Mallawany of Ortiz's Civil Division and Daniel Zytnick of the Justice Department's Consumer Protection Branch.

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